

REMARKS

1. The Amendments and the Support Therefor

Five claims (2-4 and 20-21) have been canceled, five new claims (27-31) have been added, and claims 1, 19, and 24 have been amended to leave claims 1, 5-13, 15-19, and 22-31 in the application. No new matter has been added by the amendments or new claims, wherein:

- *Independent claim 1* has been amended to incorporate its dependent claims 2-4, with support also being found in the drawings;
- *Claim 19* is amended for clarity;
- *Claim 24* is amended to correct dependency;
- *Claims 27-28 and 30-31* find support in the drawings;
- *Claim 29* finds support at page 3 lines 21-27 and page 9 line 28 onward (also see discussion at Section 7 of this Response).

2. Information Disclosure Statement (Form PTO-1449)

Please note that a form 1449, with fee, is submitted with this Response to make WO 02/083012 to *Tasci* of record.

3. Sections 1-2 of the Office Action: Objections to the Drawings / Claims

The objections are addressed by the cancellation of claims 20-21.

4. Sections 3-6 of the Office Action: Rejection of Claims 19 and 21 under 35 USC §112

These rejections are addressed by a clarifying amendment to claim 19, and by the cancellation of claim 21.

5. Sections 8-14 of the Office Action: Rejection of Claims 1-5 and 7-8 under 35 USC §102 in view of U.S. Patent 6,408,889 to *Komachi*

These rejections are addressed by the amendment to claim 1 to recite the ball/projection/slot/socket arrangement previously recited in claims 2-4, and shown in the drawings. *Komachi* plainly does not have a male part including a ball *and* a pair of projections,

and a female part including a socket *and* a slot, as recited in claim 1. Later rejections (e.g., at Sections 10-11 and 29-30 of the Office Action) appear to imply that *Komachi*'s element 13 (FIG. 2) is a "ball" with "projections" 13a, and element 12a is a socket/slot. However, it cannot fairly be said that element 13 is a "ball" as recited: under no reasonable definition of the word "ball" can a thin flange (such as *Komachi*'s element 13) be regarded as a "ball," even if rounded/radiused. It is accepted that during examination, the USPTO must interpret the claims using their broadest reasonable interpretation (MPEP 2111). Words in a claim are therefore given their plain meaning unless a contrary definition is provided in the specification (MPEP 2111.01). Further, the "plain meaning" to be applied to words in a claim is the meaning applied by those of ordinary skill in the art, *not* the meaning ascribed to the term by laymen or others (MPEP 2111.01). Extrinsic references such as dictionaries may provide evidence of the meaning of claim terminology, so long as the dictionary meanings are otherwise consistent with the Applicant's usage (MPEP 2111.01). Where a claim term is an everyday word which is not assigned a special or limited meaning by the specification, it is acceptable to look to a dictionary to determine the meaning that should be given to the term. *Optical Disc Corp. v. Del Mar Avionics*, 54 USPQ2d 1289, 1295 (Fed. Cir. 2000); *Vanguard Products Corp. v. Parker Hannifin Corp.*, 57 USPQ2d 1087, 1089 (Fed. Cir. 2000). Here, looking to common dictionaries, a "ball" is defined as:

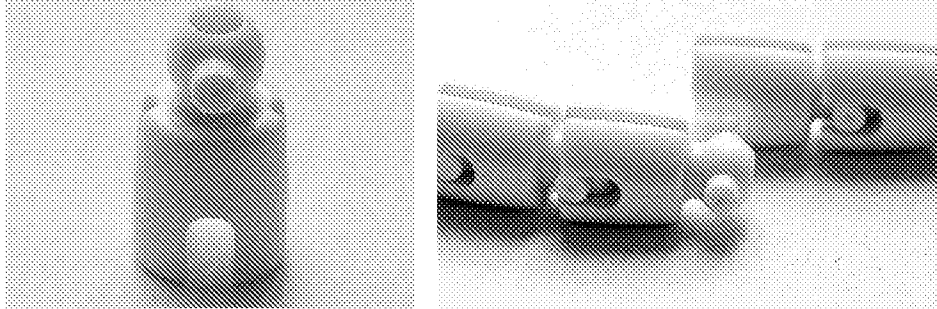
- "something spherical or almost spherical, especially a spherical mass or arrangement of material" (Encarta World English Dictionary, [http:// encarta.msn.com/dictionary_1861728457/ definition.html](http://encarta.msn.com/dictionary_1861728457/definition.html));
- "1a. A spherical object or entity: a steel ball. b. A spherical or almost spherical body: a ball of flame." (The American Heritage Dictionary of the English Language, [http:// www.bartleby.com/ 61/ 21/ B0042100.html](http://www.bartleby.com/61/21/B0042100.html))
- "a solid or hollow sphere, especially one that is kicked, thrown, or hit in a game" (Compact Oxford English Dictionary, [http:// www.askoxford.com/ concise_oed/ ball_1?view=uk](http://www.askoxford.com/concise_oed/ball_1?view=uk))

In view of these definitions, it is clear that *Komachi* does not include the recited "ball." Moreover, *Komachi*'s element 13 does not include a "pair of projections" unless two opposing

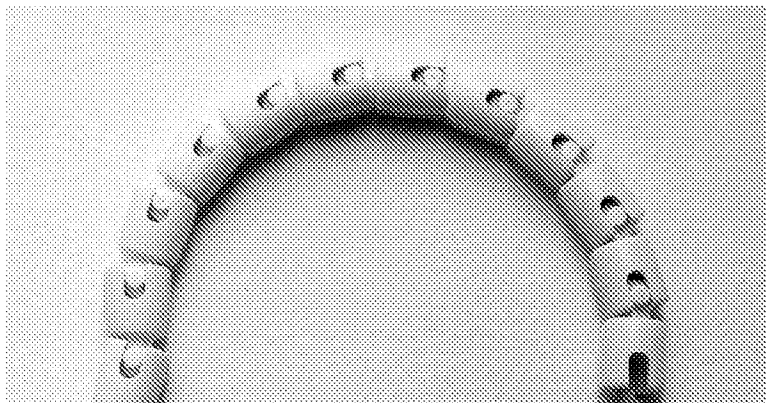
elements 13 and their “projections” 13a are considered – and two opposing elements 13 certainly do not have a “ball” structure under any reasonable interpretation of that term. Further, while through-holes 12a might be “sockets,” they are not “slots” – they have no elongation/length – and it is simply not seen how *Komachi* can be regarded as including both a socket *and* slot.

Further, when *Komachi* is reviewed in combination with all other references of record, it is in no way apparent how an ordinary artisan having no knowledge of the invention would be led to contemplate the claimed invention. The recited structure is simply in no way foreseeable in view of the prior references of record. It is also notable that the claimed device offers a substantial advancement over the devices illustrated in the references of record. As shown in the following images, the embodiment shown in the application’s drawings allows *each* segment to pivot about the X *and/or* Y axis of an adjacent segment. Compare to *Komachi*, wherein each segment only pivots in *one* axis with respect to an adjacent segment (e.g., in FIG. 2, each segment may only pivot about the axis defined by the through-hole 12a and protrusion 13a with respect to its adjacent segment). *Komachi* does describe an arrangement allowing two-axis bending at column 7 lines 6-10; here, the arrangement basically corresponds to that of *Komachi*’s FIG. 2, but here one end of a segment is rotated 90 degrees with respect to the other end of the segment (like the arrangement of FIG. 6 of U.S. Patent 5,749,828 to *Solomon*). Consider that in these *Komachi* / *Solomon* embodiments, one can only achieve a bend about an axis (e.g., the Y axis or Z axis in FIG. 6 of *Solomon*) *every two* joints, rather than at *every* joint, as in the applicant’s embodiment illustrated below. The applicant’s illustrated embodiment thus allows for bending with a much smaller radius of curvature (i.e., far “tighter” bends). In addition, the ball-and-socket arrangement of the illustrated embodiment transmits any thrusting forces along the axis of the device, rather than at the circumference of the device, as in *Komachi* and *Solomon*. This allows for easier manipulation – when bending the device, one does not need to work as much to oppose thrusting forces – as well as greater strength.

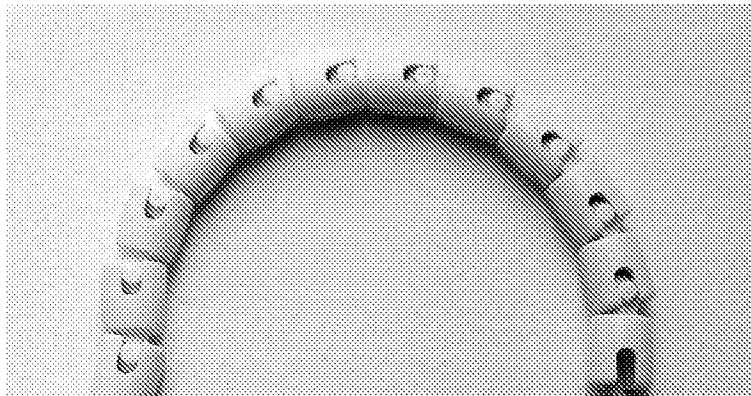
Individual Link



Flexion Around Ball Joint and
Centre of lateral projections



Flexion Around Ball Joint and
Centre of lateral projections



In summary, the illustrated embodiment performs better and is stronger than the known prior devices, and as should be evident from comparing the illustrated embodiment to those of the cited references, the illustrated embodiment can be made more inexpensively and easily. In view of the superiority of the illustrated embodiment over those of the cited references, we submit that if the illustrated embodiment was in any way obvious in view of the references of record, it surely would have been developed and placed in use by others by now – but to the best of applicant’s knowledge, it hasn’t been. Since the matter of claim 1 is both novel and unobvious, kindly allow claim 1 and its dependent claims 2-15.

6. Sections 21-22 of the Office Action: Rejection of Claims 6 and 16-26 under 35 USC §103(a) in view of U.S. Patent 6,408,889 to *Komachi* and U.S. Patent 5,749,828 to *Solomon*

The rejection of claim 6 is believed to be addressed for the reasons noted in the foregoing Section 5 of this Response.

Regarding the rejection of claim 16 and its dependent claims 17-26, kindly reconsider and withdraw the rejections since *Solomon* would not in fact lead an ordinary artisan to contemplate a “catheter having a catheter interior passage [wherein] the segments are translatable within the passage, whereby the segment at one end of the line can . . . be advanced through at least a major portion of the length of the catheter interior passage to eject the medical implant from a passage exit.” Initially, as to the statement in the rejection that:

Regarding the limitations, "whereby the line of segments may adopt a curved path within the catheter", "whereby the segment at one end of the line can: have a medical implant situated thereon, and be advanced through at least a major portion of the length of the catheter interior passage to eject the medical implant from a passage exit", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576,152 USPQ 235 (CCPA 1967)).

While a method of use may not be germane to the patentability of device claims, structural or functional limitations recited by the claims cannot be disregarded. See MPEP 2114; 2111.04. Here, the claim states that segments are “adjacently arrayed in a line within the catheter interior passage,” and “the segments are translatable within the passage” and that a segment at one end of the line can “be advanced through at least a major portion of the length of the catheter interior

passage”. These limitations recite structural and functional limitations, and cannot be disregarded.

Turning then to the cited column 4 lines 23-27 of *Solomon*, this passage reads as follows:

The bending neck 20 may be encased with a continuous elastomeric jacket (not shown) to seal the links 2, the sleeves 12, the cables 13 and other components housed within the bending neck 20 from the patient's body elements. The elastomeric jacket is similar to those used in the art to encase endoscopes, transesophageal ultrasound probes and other invasive medical devices designed for insertion into the body cavities. The smooth surface of the elastomeric jacket provides for easier insertion of the bending neck 20 into the body cavities.

In essence, *Solomon* states that the articulated device – best visualized with respect to FIGS. 4A-4B – can be “encased” within a tightly-fitting jacket so that it can be more easily inserted into the body, and so that it is isolated from the patient’s body interior. These concerns are evident when the *Solomon* device is viewed, since its outer surface is not smooth, and would be difficult to clean after use. *Solomon* certainly teaches that the jacketed device may be translated within the body, but *Solomon* does not in any way suggest that it would be beneficial to have the articulated device translate *within the jacket*. Consider that if this was the case, once the jacketed device was inserted within the body, upon withdrawal of the device, the jacket could slip therefrom and be left trailing within the body. Thus, after reviewing *Komachi* and *Solomon*, an ordinary artisan might be led to contemplate fitting a tightly-fitting jacket over the articulated device of *Komachi*, again to allow it to be more easily inserted into the body, and so that it is isolated from the patient’s body interior. However, it cannot fairly be said that one would have *Komachi* translatably ride within a catheter, such that a segment within the catheter can be advanced through a major portion of the catheter’s length. As noted by MPEP 2141, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” (citing *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007)). Here, there is no articulated reasoning as to why an ordinary artisan would contemplate having *Komachi* (as modified by *Solomon*) translate within the interior passage of a catheter, as opposed to having a tightly-jacketed device translate within a body. Kindly withdraw the rejections.

Regarding claim 24, which recites that “each segment bears a ball thereon, and wherein the projections extend from the ball”, this is addressed in the foregoing Section 5 of this Response: under no reasonable interpretation of the term “ball” can *Komachi* be regarded as including a “ball.”

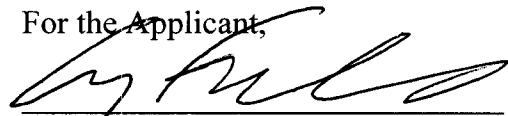
7. New Claims 27-31

New claims 27-31 are submitted to be allowable for at least the same reasons as their parent claims. It is noted that new claim 29 further distinguishes the catheter of claim 29 from the “jacket” of *Solomon* discussed at the foregoing Section 6 of this Response. New claim 30 is submitted to be independently allowable for the reasons discussed at the foregoing Section 5 of this Response.

8. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



Craig A. Fieschko, Reg. No. 39,668

CUSTOMER NO. 25005

DEWITT ROSS & STEVENS S.C.

2 E. Mifflin St., Suite 600

Madison, WI 53703-2865

Telephone: (608) 395-6722

Facsimile: (608) 252-9243

cf@dewittross.com